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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
ACC/FL/P32396		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/08048	17/08/2000	20/08/1999
International Patent Classification (IPC) or national classification and IPC A61K9/00		
Applicant SMITHKLINE BEECHAM LABORATOIRES PHARMACEUTIQUES		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10/03/2001	14.11.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Zimmer, B Telephone No. +49 89 2399 8600

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/08048

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-8 as originally filed

Claims, No.:

1-15 as originally filed

Drawings, sheets:

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3, 5-7, 12, 14, 15
	No:	Claims	1, 2, 4, 8-11, 13
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-15
Industrial applicability (IA)	Yes:	Claims	1-15
	No:	Claims	

2. Citations and explanations
   see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

   D1: WO 98 35672 A (SANROMA BORDALLO JOSE LUIS ;SMITHKLINE BEECHAM S A (ES); MENTION J) 20 August 1998 (1998-08-20) cited in the application

   D2: EP-A-0 389 177 (BEECHAM GROUP PLC) 26 September 1990 (1990-09-26)

2. Prior art document D1 discloses a sachet formulation comprising amoxycillin and clavulanate in a weight ratio of 4:1 and 7:1, silica gel, CLPVP, aspartame, micro-crystalline cellulose as well as a peach-lemon-strawberry flavour (Ex. 9).
   Due to the unclarity in claim 1 of the present application of how the modified strawberry flavour can be achieved (see also item VII) it has to be concluded that the combination of a peach and a strawberry flavour in the mixed fruity flavour as disclosed in D1 results in a modified strawberry flavour.
   Therefore, D1 is novelty destroying for the subject-matter of independent claim 1 as well as claims 2, 4, 8-11 and 13 of the present application (Art. 33(2) PCT).

3. Inventive step cannot be assessed when the requirements of novelty are not met. However, in the light of the above cited prior art, it appears that the problem underlying the present patent application lies in the provision of a formulation of amoxycillin and clavulante with an improved strawberry flavour. The claimed subject-matter, i.e. the addition of extra components to achieve a better strawberry taste has already been solved in the prior art and is therefore obvious for a person skilled in the art especially as example 10 discloses a suspension, whose qualitative and quantitative composition is identical to formulation (a) of claim 15 of the present application apart from the lack of the creamy strawberry flavour.

4. Although the subject-matter of claims 5-7, 12, 14 and 15 seems to be new in view of the cited prior art, it is not inventive (Art. 33(3) PCT).
   The addition of flavour enhancers (e.g. maltol) to enhance the aroma is common

general knowledge for a person skilled in the art. Furthermore, it is known from D2 that a composition comprising amoxycillin, Miglyol and a combination of vanilla cream flavour and strawberry flavour is extremely palatable (Ex. 2 and p. 3, l. 37-38).
Claims 5-7, 12, 14 and 15 do not appear to contain any additional features which involve an inventive step when combined with the subject-matter of any claim to which they refer especially in view of D1 (p. 13, l. 19-32) . Dependent claims are only allowable when related to a patentable independent claim (Rule 6.4 PCT).

Re Item VII
Certain defects in the international application

1. Independent claim 1 does not meet the requirements of Art. 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved which merely amounts to a statement of the underlying problem. The technical features necessary for achieving this result should be added.
Additionally, the terms "creamy" and "extra fruity" used in claim 1 are vague and unclear (Art. 6 PCT).

2. The expression "preferably" employed in claim 14 relates to preferred modes which should be claimed in dependent claims.

3. The abbreviation "CLPVP" (claims 13 and 15) is not generally accepted in the art, contrary to the requirements of Rule 10.1(e) PCT.